EXHIBIT 1

Filed in Madison District Court
*** EFILED ***
Case Number: D07CI200000264
Transaction ID: 0011230458
Filing Date: 07/09/2020 01:24:48 PM CDT

District Court, Madison County, Nebraska

Karen Ellen Jackson and Daniel Jackson, **Plaintiffs,** **v.** **Sanofi-Aventis US LLC;** **Sanofi US Services, Inc.;** **Chattem Inc.;** **Boehringer Ingelheim Pharmaceuticals, Inc.,** **and** **Pfizer, Inc.** **Defendants.**	**Case No.: CI 20-_____** **Complaint** **Jury Demand** **And** **Trial Location Selection**

Contents

Plaintiffs allege:

Overview

1. Karen Ellen Jackson and Daniel Jackson, husband and wife, sue for Mrs. Jackson's personal injuries and Mr. Jackson's derivative consortium claim. Plaintiff, Mrs. Karen E. Jackson, (hereafter where Plaintiff is singular it refers to Mrs. Jackson unless stated otherwise) contracted bladder cancer, diagnosed in April, 2020. Her cancer was caused by the drug Zantac® also known generically as Ranitidine. Zantac® has been recalled by the U.S. Food and Drug Administration because it causes cancer in human users. It is classified as probably carcinogenic by the World Health Organization, the International Agency for the Research of Cancer, the United States Food and Drug Administration, and the governing bodies of numerous other governments.

2. Zantac® was partially pulled from the shelves in the United States about March 20, 2020 after information surfaced in September 2019 that the substances within Ranitidine are highly carcinogenic. On April 1, 2020 all Zantac® products were ordered recalled from all sources by the FDA.[1] Earlier, on October 18, 2019, Defendant Sanofi-Aventis US LLC announced publicly that Zantac® 150, Zantac® 150 Cool Mint, Zantac® 75 (OTC Products) were voluntarily recalled by it following an alert by the FDA on September 13, 2019 that "some ranitidine medicines, including Zantac® OTC, could contain NDMA at low levels and asked manufacturers to conduct testing."[2]

3. Plaintiffs sue for special and general damages.

Jurisdiction, Venue, Parties

4. The District Court has subject matter jurisdiction pursuant to *Neb Rev Stat* § 24-302. Venue is proper in Madison County, Nebraska where Plaintiffs reside, the Zantac® medication was sold and ingested, and where substantial part of the activity giving rise to this claim occurred. *Neb Rev Stat* § 25-403.01. Each and all defendants contracted

[1] FDA Public Announcement at https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market

[2] Sanofi company announcement 10.18.2019 posted by FDA at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sanofi-provides-update-precautionary-voluntary-recall-zantac-otc-us

to sell and sold Zantac® in Nebraska and caused tortious injury to Plaintiffs here. They are subject to the jurisdiction of Nebraska courts pursuant to *Neb Rev Stat* section 25-536.

5. Plaintiffs are Karen Ellen Jackson, born in 1949 (where used in singular "Plaintiff" refers to her) and his spouse Daniel Jackson. Plaintiffs married in 1970. Plaintiff suffers from cancer caused by Zantac®. They reside in Nebraska.

6. The Defendants are:

6.1. Sanofi-Aventis US LLC, a Delaware limited liability company. Its principle place of business is at 55 Corporate Drive, Bridgewater, New Jersey, 08807. It is believed to be a wholly owned subsidiary of a French company named Sanofi.

6.2. Sanofi US Services Inc., a Delaware corporation. Its principle place of business is also at 55 Corporate Drive, Bridgewater, New Jersey, 08807. It is also believed to be a wholly owned subsidiary of the French company, Sanofi.

6.3. Chattem Inc., a Tennessee corporation with its principle place of business at 1715 West 38th Street, Chattanooga, Tennessee, 37409. It is also believed to be a subsidiary of the French company, Sanofi.

6.4. Boehringer Ingelheim Pharmaceuticals, Inc. ("BIP"). BIP is a Delaware corporation with its principle place of business at 900 Ridgebury Road, Ridgefield, Connecticut, 06877. It is a subsidiary of the German company Boehringer Ingelheim Corporation.

6.5. Pfizer, Inc., manufactured and controlled Zantac® from at least 2000 through 2006 and became the successor to the liabilities of Warner-Lambert, Inc., which it acquired and merged into Pfizer in 2000. Pfizer through its own direct ownership after acquiring Warner-Lambert and prior to them was responsible for the marketing and distribution of Zantac® from approximately 1990 or earlier to 2006 when it sold the product to Defendant Boehringer Ingelheim

Pharmaceuticals, Inc. Pfizer was the original NDMA holder for OTC Zantac®.

No Defendant has a registered agent in Nebraska, except Pfizer, Inc. Pfizer, Inc.'s Registered Agent is CT Corporation System, 5601 South 59th Street, Suite C, Lincoln, NE 68516. All other Defendants are subject to the jurisdiction of Nebraska courts because they contracted to sell and deliver Zantac® here and caused tortious injuries to Plaintiffs here.[3] Service of process may be made as provided by the Nebraska Business Corporations Act.[4]

7. Sanofi-Aventis US LLC, Sanofi Services Inc. and Chattem Inc. (collectively "Sanofi" or sometimes "Sanofi Defendants") control the U.S. rights to Zantac® and have do so since January 2017.[5] They are the successors in interest to BIP.

8. The Sanofi Defendants manufactured and distributed Zantac® in the United States during this period. Plaintiff routinely used Zantac® manufactured and distributed by the Sanofi Defendants.

9. At relevant times between October 2006[6] and January 2017, BIP owned the U.S. rights to Zantac® and manufactured and distributed it in the United States during that period. Plaintiff used BIP's Zantac® throughout this time. BIP acquired Zantac® from Pfizer as alleged in ¶ 6.5 above, and Pfizer controlled it prior to that time.

10. Prior to October 2006, Pfizer owned the US rights to over-the-counter and prescription Zantac®. Pfizer sold and distributed the product through physicians and pharmacies in Nebraska and Plaintiff acquired and used its product as with the other defendants.

Factual Allegations

11. Plaintiff enjoyed generally good health from the time of her birth until April, 2020. As a singular exception, Plaintiff did suffer from Type I diabetes controlled by

---

[3] *Neb Rev Stat* § 25-536.
[4] *Neb Rev Stat* § 21-2,212(b).
[5] Pare, Mike, *Chattem adds Zantac, Dulcolax to portfolio*, Chattanooga Times Free Press (Tenn.) (Feb. 8, 2017).
[6] Boehringer Ingelheim Pharmaceuticals Inc. *Announces Agreement to Acquire Zantac from Johnson & Johnson and Pfizer Consumer Healthcare Business*, Business Wire (Oct. 12, 2006)

medication. She did have acid reflux and indigestion problems requiring antacid medications.

12. Plaintiff used:

12.1. Prescription Zantac® and only occasional non-prescription dosages. She is believed to have commenced to use approximately 1990 and used thereafter on a daily basis, almost exclusively pursuant to prescriptions, supplementing with over the counter medications only when her prescriptions expired, and she was unable to fill them immediately, and is believed to have used dosages of 150 mg. Her medication was prescribed by the U.S. Indian Health Service.

12.2. When over the counter Zantac® was purchased, it was generally purchased at Norfolk, Nebraska or Madison, Nebraska pharmacy.

13. Plaintiff has no history of bladder cancer and no history of other cancers of the stomach or abdominal tract, intestinal or similar cancers in her family background. She has no genetic or other pre-dispositions to renal cancer. Plaintiff has not smoked, has generally been in reasonable control of her weight, has not suffered hypertension or been treated for bladder failure and has not suffered from syndromes that cause an increase in the risk of bladder cancer. She has not suffered from:

- Von Hippel-Lindau Disease
- Birt-Hogg-Dube Syndrome
- Tuberous Sclerosis Complex
- Hereditary Papillary Renal Cell Carcinoma
- Familial Renal Cancer
- Exposure to Cadmium
- Exposure to herbicides with known associations with Renal Cancer
- Overuse of medications.
- Hypertension

14. In April, 2020 Plaintiff was diagnosed with bladder cancer. She is presently under active treatment, including extensive surgery for removal of the bladder and other organs on June 19, 2020. Her prospects for successful treatment leading to remission and eventually freedom from cancer, are not known. Plaintiff is presently ill. She expects to live with the presence or threat of cancer or recurrent cancer for the rest of her life.

15. Plaintiff's illness imposes burdens upon her spouse as her caregiver. Since her ability to engage in the activities of daily living, and her employment, are diminished, Mr. Jackson is deprived of his wife's care, comfort and companionship, support, services, advice, counsel, love and affection as it would be extended normally. She is also called upon to provide emotional and physical comfort care and support and expects to be required to do so throughout her battle against cancer in her body. Mr. Jackson claims general damages for his consortium injuries.

16. Plaintiff's work life and personal life are disrupted by her diagnosis. Her cancer diagnosis has caused and continues to cause depression, anxiety, sleep disturbance, loss of self-confidence, diminished ability to focus and be attentive, and disturbance of his mental health and status. She expects to require and receive assistance to battle these mental and emotional elements of his illness on a long-term basis.

17. Plaintiff also experiences and expects to continue to experience physical and emotional pain, illness, discomfort, and physical distress, loss of strength, diminished stamina, and general inability to perform her activities of daily living and work, on a temporary basis. It is expected that these circumstances will be permanent, although the degree of permanence is not yet known. Plaintiff recognizes that her cancer diagnosis produces a shortened life expectancy. Before her cancer, she had a foreseeable life expectancy of at least 16.54 years.[7] She is now permanently physically impaired. While Plaintiff suffered from diabetes, she was employed full time and in satisfactory health for her age and circumstances.

[7] U.S. Social Security Administration, https://www.ssa.gov/oact/STATS/table4c6.html

18. While Plaintiffs' special damages are accruing and are not fully known, they are expected to include:

18.1. Lost earnings

18.2. Lost earning capacity

18.3. Medical expenses for physicians and medical institutions

18.4. Pharmacological and pharmaceutical expenses

18.5. Emotional health services

18.6. Expenses for travel to and from medical care.

19. Leave is requested to amend this Complaint to plead the precise amount of special damages incurred as of the time of the pre-trial conference, or at trial, when these are known.

A. Plaintiff's Use of Zantac®

20. By March, 2020, Plaintiff had used Zantac® extensively. However, had she known the risks and had they been disclosed to her and other consumers on the drug's label and through other means, she would not have used it. Neither Sanofi nor BIP disclosed to consumers that Zantac® has a critical defect that because it produces high quantities of N-Nitrosodimethylamine ("NDMA"), a chemical the World Health Organization's International Agency for Research of Cancer ("IARC") classified as "clearly carcinogenic".

21. Plaintiff used Zantac® with her physician's knowledge who directed she use by prescription as disclosed in her medical records. However, she estimates she used it for at least thirty (30) years and used it daily in dosage by prescription of approximately 150 mg per day. Total ingestion, 150 mg x 365 days x 30 years (min.) = **1,642,500 mg**.

22. Throughout the time Plaintiff used Zantac® she used the drug products in accordance with their directions and for their intended purposes. She did not alter or modify the Zantac® products and used them as packaged and sold, with no changes.

B. Zantac® OTC

23. Until recalled from the market in 2020, for many years, Zantac® was the most popular over-the-counter medication, also available in prescription dosages, to

decrease stomach acid, reduce heartburn and acid indigestion, treat or ameliorate the anguish of gastric ulcers, and reduce the adverse consequences of "sour" stomach and other gastro intestinal conditions.[8] Zantac® was developed in 1983 and became available as a non-prescription drug in some dosages in 1995. Its generic version became available the following year.

24. Zantac® is the Sanofi and brand name version of the drug ranitidine. Zantac® was first sold in the United States in 1983. Within three (3) years, its sales volume reportedly exceeded $1.0 billion in sales.[9] Zantac® remained among the most widely used and popular tablet brands of antacid in the United States through 2018 and into 2019.[10] Plaintiffs believe this likely continued until the product was recalled in 2020. While

25. Zantac® is widely referred to as an antacid and used for this purpose without consumers focusing on the distinction between neutralizing acids in the stomach and preventing their production.[11]

26. Plaintiff occasionally used over-the-counter Zantac®, most probably in 150 mg dosages, she more routinely used the medication by prescription by her physicians as shown in her medical records. Zantac® has an adverse, clearly carcinogenic effect on the human body. When ingested, Zantac® produces within the body quantities of a deadly chemical known as N-Nitrosodimethylamine (NDMA). The World Health Organization described this medication as clearly carcinogenic.[12]

27. Ranitidine is called an H2-receptor antagonist. It was commonly prescribed for gastro esophageal reflex disease (GERD) as well as for peptic ulcers and other matters.

---

[8] Richard Wright, M.D. *How Zantac Became the Best-Selling-Drug in History* 16(4) J.HealthcareMarketing24 (Winter 1996)

[9] *Id.*

[10] While Zantac is routinely referred to as an antacid, it actually has a mode of action that works by reducing the amount of acid the stomach makes, instead of by neutralizing acids already produced by the stomach. Ranitidine, oral tablet, health line, https://www.healthline.com/health/ranitidine-oral-tablet.

[11] *See Leading Antacid Tablet Brands in the United States in 2018 Based on Sales,* Statista (https://www.statista.com/statistics/194544/leading-us-antacid-tablet-brands-in-2013-based-on-sales/).

[12] RG Liteplo et al. *Concise International Chemical Assessment Document 38*, N- Nitrosodimethylamine, World Health Organization (2002), https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

H2-receptor antagonist (H2RAs) selectively block the histamine-2 receptor in gastro parietal cells. This produces decreased production of gastric acid.[13]

28. Ranitidine produces NDMA in the body. Testing by independent laboratories in 2019 established dramatically elevated levels of NDMA produced in the bodies of patients who used Zantac® and other Ranitidine products. N-Nitrosodimethylamine (NDMA) is an organic chemical known to be in a family of potent carcinogens, the dangers of which to human health have been recognized since at least 1979 when researchers observed that it caused cancer in nearly every laboratory animal tested. NDMA is so dangerous that it is no longer produced or commercially used in the United States except for research, and then only as a poison.

29. The International Agency for Research of Cancer (IARC) classified NDMA as a group two (2) "probably carcinogenic to humans" substance.[14] the US Environmental Protection Agency also classified NDMA as a probable human carcinogen. As early as 1980 products with unsafe levels of and DMA were recalled by manufacturers or at the direction of the FDA.

30. In 2014, research scientists conducting a case control study in Newfoundland and Labrador in Ontario Canada found an increased risk of gastrointestinal cancer in humans ingesting Zantac® and ranitidine.[15] Doses of ranitidine in combination with nitrite produce DNA fragmentation in animal studies[16], and adverse consequences in humans were found by researches.[17]

31. On July 13, 2018, heart medications found to produce unsafe levels of NDMA in the human body were recalled by the FDA because they did not meet FDA safety

---

[13] *Id.*

[14] IARC, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1-42, *IARC Monograph Evaluation Carcinogenic Risks Human Supplement 7, 1-440 (1987)*.

[15] ZHU, Y et al. Dietary N-Nitroso compounds and risk of colorectal cancer: A case control study in Newfoundland and Labrador in Ontario Canada, 111 British Journal of Nutrition 1109-117 (2014).

[16] Brambilla, G. et al., Genotoxic effects in rodents given oral doses of ranitidine and sodium nitrite, for carcinogenesis 1281-1285 (1983)

[17] Zeng & Mitch, WA, *Oral Intake of Ranitidine Increases Urinary Excretion of N- Nitrosodimethylamine*, 6 carcinogenesis 625-634 (2016).

standards.[18] These recalls stemmed from detection of an impurity called N-nitrosodimethylamine (NDMA) -- a probable human carcinogen -- in the valsartan active pharmaceutical ingredient (API) the affected products contained.[19]

32. In Autumn of 2019, testing laboratories Valisure LLC and Valisure RX LLC (together "Valisure") detected extraordinarily high NDMA levels in all lots of ranitidine tested across multiple manufacturers of products including Zantac®.[20] Valisure notified the FDA of its filings September 13, 2019. Valisure is an online pharmacy licensed in at least thirty-eight (38) states. It has an analytical laboratory that it is accredited by the International Organizations for Standardization. Valisure is also registered with the Drug Enforcement Agency of the United States and the US Food and Drug Administration. Valisure's test established that "ranitidine can react with itself in standard analysis conditions…at a high efficiency to produce NDMA dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen."[21]

33. The FDA announced a human permissible intake maximum limit of 96 ng of NDMA per day.[22] Yet, more than thirty (30) years ago the Agency for Toxic Substances and Disease Registry warned that NDMA, in high quantities, was dangerous and the exposures to NDMA caused liver damage in laboratory animals and usually resulted in internal bleeding and death.[23]

34. The Valisure testing, using gas chromatography and mass spectrometry ("GC/MS") testing as prescribed by the FDA detected 2,511,469 ng of NDMA per 150 mg

---

[18] FDA Announcement, July 13, 2018, https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity

[19] AAFP NEWS STAFF, July 25, 2018, https://www.aafp.org/news/health-of-the-public/20180725valsartan.html

[20] Valisure Citizen Petition to FDA ("Citizen Petition") at 6 available, https://hbw.pharmaintelligence.informa.com/~/media/Supporting%20Documents/Rose%20Sheet/2019/09/9%20Sept%202019%20Valisure%20Ranitidine%20Petition.pdf

[21] *Id.*

[22] *FDA Updates and Press Announcements on Angiotension II Receptor Blocker (ARB) Recalls*, FDA (updated August 28, 2019) (Setting "Interim Limits for NDMA")

[23] Agency for Toxic Substances & Disease Registry, *Public Health Statement for N- Nitrosodimethylamine 2* (December 1989), https://www.atsdr.cdc.gov/ToxProfiles/tp141-c1-b.pdf.

tablet of Zantac®. The FDA protocol detected NDMA in each Zantac® tablet at an order of magnitude of more than 25,000 times the FDA permissible intake limit.

35. The National Institutes of Health noted that the typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 350 mg once nightly for four (4) to eight (8) weeks with maintenance doses of 150 mg once daily.[24]

36. This means that a user of the Zantac® medications like the Plaintiff would, over the course of eight (8) weeks when using the substance for its intended purpose to treat a peptic ulcer would be exposed to more than 280,000,000 ng (0.28 grams) of NDMA. A consumer like Plaintiff taking 150 mg maintenance doses of Zantac® is exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a single year. Yet, the NDMA permissible intake limit is 96 mg per day or 0.000034 grams per year. Plaintiff was a foreseeable human user of Zantac®. The product he used reached him in the same condition it left its manufacturer; it was used as intended for intended purposes.

37. When Valisure tested Zantac® in conditions simulating the human stomach, it detected NDMA in quantities as a high as 304,500 ng per tablet. This would be approximately more than 3,150 times the amount that can be safely ingested daily.

38. The dangers of Zantac® became publicly known on or about September 13, 2019 when the Valisure filings were made and disclosed, and the FDA registered and responded to them. Nonetheless, some countries and the United States took steps to protect the public from ranitidine before the US, FDA acted, Health Canada, the nation's health department, compelled the cessation of distributions in Canada in September 2019.[25]

---

[24] *Drug Record: Ranitidine, Regular Type National Institutes of Health* (updated July 1, 2019), https://livertox.nih.gov/ranitidine.htm.

[25] *Information Update – Health Canada requests that companies stop distributing ranitidine drugs in Canada while it assesses NDMA: Some products being recalled*, Cision Canada (September 17, 2019) https://www.newswire.ca/news-releases/information-update-health-canada-requests-that-companies-stop-distributing-ranitidine-drugs-in-canada-requests-that-companies-stop-distributing-ranitidine-drugs-in-canada-while-it-assesses-ndma-some-products-being-recalled-821911993.html

39. Other nations including Germany, Switzerland, Australia and Italy initiated drug recalls months before the United States acted. Singapore, Qatar, Pakistan all halted sales.[26]

40. Some private companies promptly stopped distribution of its product, worldwide. This was true of Sandoz, a unit of Novartis AG.[27]

41. The FDA's statement alerting patients and healthcare professionals of NDMA found in ranitidine samples was issued September 13, 2019. It alerted Defendants and all in the public of the concerns.[28]

42. Even after September, the FDA was slow to act and did not recall the medication until March 2020. In the interim, the FDA referred to an "impurity" in Zantac® as opposed to the science in testing of the product revealing that the formation of NDMA in the human body is the result of the chemical structure of ranitidine and its changes within the body and not any impurity. Simply, the formation of Zantac® itself is defective in its design, and its structural molecular and chemical design and distribution makes it inherently dangerous, carcinogenic, and deadly to humans.

---

[26] Tom Gallen, *Ranitidine Recalls Begin In Europe As Regulators Take Action,* Pharma Intelligence (Sept. 18, 2019), https://hbw.pharmaintelligence.informa.com/RS149219/Ranitidine-Recalls-Begin-In-Europe-As-Regulators-Take-Action; *Pharmacies pull heartburn meds over contamination concerns,* Uutiset (Sept. 19, 2019), https://yle.fi/uutiset/osasto/news/pharmacies_pull_heartburn_meds_over_contamination_concerns/10977530; PB Jayakumar, *Anti-acidity drug ranitidine gives heartburn to industry and public,* Business Today (Sept. 24 2019), https://ww.businesstoday.in/sectors/pharma/anti-acidity-drug-ranitidine-gives-heartburn-to-industry-and-public/story/380916.html; *Singapore halts sales of some antacids over stomach cancer concerns*, South China Morning Post (Sept. 16, 2019), https://www.scmp.com/news/asia/southeast-asia/article/3027521/singapore-halts-sales-some-antacids-over-stomach-cancer; *Health ministry recall Zantac as a precautionary measure,* Qatar Tribune (Sept. 16, 2019), https://www.qatar-tribune.com/news-details/id/172460; Rava Rizvi, *DRAP Orders Recall of Medicine That Can Cause Cancer*, Prokpakistani (Sept. 24, 2019), https://propakistani.pk/2019/09/24/drap-orders-recall-of-medicine-that-can-cause-cancer/?utm_source=rss&utm_medium=rss&utm_campaign=drap-orders-recall-of-medicine-that-can-cause-cancer.; *UAE suspends medicine with ranitidine,* Expat Media (Sept. 24, 2019), https://www.expatmedia.net/uae-suspends-medicine-rantidine/2019/09/.

[27] Anna Edney, Carcinogens Scare Sets Off Global Race to Contain Tainted Zantac, Bloomberg (Sept. 18, 2019) and *Dr. Reddy tumbles on buzz halting all supply of Ranitidine*, Business Standards (September 23, 2019).

[28] FDA, *Statement alerting patients and healthcare professionals of NDMA found in samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-NDMA-found-samples-ranitidine.

43. Even after the revelations of September 2019, Sanofi refused for more than a month to withdraw its drug or halt its distribution. It did so only in Canada where the government ordered that it do so.[29]

44. For a month, Sanofi and BIP refused to act and refused to inform the public. They also refused to modify their drug to make it safe or withdraw it. These refusals occurred even though both Sanofi and BIP knew or had reason to know that unsafe and carcinogenic levels of NDMA were produced in the human body of Zantac®'s users. Numerous scientific studies disclosed this and were or should have been known to sophisticated research and pharmaceutical companies like the Defendants.[30]

45. Zantac® was developed by GlaxoSmithKline and approved as a prescription by the FDA in 1983.[31] Sales were the product of a significant and aggressive marketing strategy. In 1996 Zantac® became available without a prescription.[32] Generic versions became available thereafter, but Plaintiff generally used the brand name Zantac® product.

C. NDMA Is Dangerous

46. NDMA is dangerous. It is an organic chemical that forms in both industrial and natural processes and it is a member of the N-Nitrosamine, a group of potent carcinogens.[33] NDMA has long been known to be carcinogenic to humans and as long ago

---

[29] Anna Edney, *Carcinogen scare sets off global race to contain tainted Zantac*, Los Angeles Times (Sept. 18, 2019), https://www.latimes.com/business/story/2019-09-18/carcinogen-scare-tainted-zantac.

[30] See, e.g., Massimiliano Sgroi, et al., *N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review of formation and removal*, 191 Chemosphere 685 (Oct. 15, 2017; Yong Dong Liu, et al., *Formation Mechanism of NDMA from Ranitidine, Trimethylamie, and Other Tertiary Amines during Chloramination: A Computational Study*, 48 Envtl. Sci. & Technology 8563 (June 26, 2014); Julien Le Roux, et al., *Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation*, 45 Water Research 3164 (Mar. 26, 2011); Ruqiao Shen & Susan A. Andrews, *Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection*, 45 Water Research 944 (Oct. 13, 2010); Giovanni Brambilla & Antonietta Martelli, *Update on genotoxicity and carcinogenicity testing of 472 marketed pharmaceuticals,* 681 Mutation Research 209 (Sept. 19, 2008; Giovanni Brambilla & Antonietta Martelli, *Genotoxic and carcinogenic risk to humans of drug-nitrite interaction products,* 635 Mutation Research 17 (Dec. 6, 2006); Zeng & Mitch, *supra* footnote 15.

[31] Write, *supra* footnote 3 at 26

[32] *Id.* At 28.

[33] *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA), Environmental Protection Agency* (Jan. 2014) https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf

as 1979 it was known to have caused cancer in virtually every laboratory animal tested for a reaction to it.[34] A 1983 publication disclosed genotoxicity evidence of carcengenotoxicity in rats given ratinidine.[35]

47. NDMA has been demonstrated as a cause of gastric cancer.[36] It is also demonstrated to cause bladder cancer.

48. The Defendants knew or should have known of all the science that disclosed the risks and hazards of NDMA and the fact that Zantac® causes its formation in the body due to Zantac®'s chemical composition and the reaction of those chemicals within the body. As early as 1980, consumer products with unsafe levels of NDMA and other nitrosamines were recalled by manufacturers either voluntarily or as directed by the FDA.[37]

49. By 2004 the risk of bladder and related cancers caused by ranitidine was becoming well established in the scientific community.[38] Defendants also knew of the World Health Organization's publications in 2008 concerning NDMA and drinking water.[39]

50. Despite awareness of these publications, research findings, and undisputed science, the Defendants continued to market and promote Zantac® and ranitidine products

---

[34] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life,* The Globe and Mail (Canada) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water,* The Globe and Mail (Canada) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); S.A. Kyrtopoulos, *DNA adducts in humans after exposure to methylating agents,* 405 Mutation Research 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[35] Brambilla et al., Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite, 4 Carcinogenesis10, 1281-1285 (1983).

[36] La Vecchia et al, Nitrosamine intake and gastric cancer risk, 4 Europ. J. Cancer. Prev. 469– 474 (1995); Pobel et al, Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in Marseille, France, 11 Europ. J. Epidemiol. 67–73 (1995).

[37] See, e.g., Karen DeWitt, *Carcinogen Fear Allayed*, The New York Times (July 2, 1980) (reporting recall of beer with higher levels of nitrosamines than permitted)

[38] Michaud et al, Peptic ulcer disease and the risk of bladder cancer in a prospective study of male health professionals, 13 Cancer Epidemiol Biomarkers Prev. 2, 250-254 (2004).

[39] *Technical Fact Sheet supra* footnote 22; WHO NDMA Guidelines for Drinking-Water Quality (3rd Ed., 2008), available at https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

as safe. It was not. Instead, it was defective in its design and the molecular structure of ranitidine, which contains both a nitrite and dimethylamine, which are well known to combine to form NDMA.[40]

51. Ranitidine, therefore, produced NDMA by reacting with itself and within itself in the human body. This means that every dosage and form of ranitidine including Zantac® exposes users to elevated dangerous levels of the carcinogen NDMA.[41]

D. Failures of Defendants to Disclose

52. Despite knowledge of these circumstances, Defendants did not disclose that Zantac® exposes users to elevated levels of NDMA or that it was carcinogenic. Even after a 2016 publication in the scientific journal *Carcinogenesis* which confirmed the production of NDMA under stomach-relevant PH conditions in living persons and that during a twenty-four (24) hour period following intake of ranitidine the quantity of NDMA in urine excreted by the patient increased by 400 times from 110 to 47,600 ng."[42]

53. Even after the *Carcinogenesis* publication, Defendants did not warn the public to withdraw their Zantac® products, or in any other way disclose the risks of its continued use.

54. The FDA did not act to protect the public. This is largely because the FDA is a regulatory agency that relies on drug manufacturers or others who submit Citizens Petitions, to deliver to it new information about approved products like Zantac®. The FDA does not normally conduct its own ongoing testing, but after a product is approved, requires some act to trigger its attention. The Defendants, as manufacturers of Zantac® an approved drug, are required to submit annual reports to the FDA containing information regarding the drug's safety and disclosing newly discovered risks, including those in published scientific studies.[43]

---

[40] Citizen Petition *supra* footnote 11 at 19.

[41] *Id*. at 1–2.

[42] Zeng & Mitch, *supra* footnote 15 at 625.

[43] 21 C.F.R. § 314.81(b)(2)

55. No disclosures were made by the Defendants. This annual report is required to include copies of unpublished reports, summaries of published reports of new toxicological findings of relevant types, and other significant publications obtained by the manufacturer concerning the ingredients in the drug.[44]

56. Defendants utterly failed to discharge this duty. Plaintiff continued to rely on representations that Zantac® was safe. These representations caused him to ingest massive quantities of ranitidine to his damage.

First Theory: Strict Liability (Failure to Warn)

57. All allegations above are renewed here.

58. Each Plaintiff contends each Defendant had a duty to exercise reasonable care to avoid physical harm to Plaintiff by preventing the recognizable and foreseeable harm it would cause by marketing its Zantac® products, and by doing so without disclosing the known carcinogenic properties of the products and their debilitating disease-inducing and life-threatening consequences for foreseeable human users. Plaintiff is one of these users. Plaintiff contends that the Defendants sold Zantac® products in a defective condition, unreasonably dangerous to consumers, including them. Defendants engaged in the business of selling the Zantac® products which they knew and expected would reach Plaintiff without substantial changes in the condition from that in which it was sold and did so reach Plaintiff. He did not misuse the product. Plaintiffs' damages are not subject to the economic loss rule.[45]

59. Each Defendant is strictly liable in tort to Plaintiffs for failure to warn of the dangers of Zantac® products. At all relevant times the Defendants each knew and each failed to act upon, report to the FDA, or disclose to the public, the known property of Zantac® to development into NDMA within the human body and thereby produced, at levels far in excess of permissible dosages, dangerous, carcinogenic NDMA known to cause cancers of the stomach, liver, kidneys, and other abdominal organs, as well as other

[44] 21 C.F.R. § 314.81(b)(2)(v)

[45] See *Lesiak v. Central Valley Ag.,* 283 Neb 103, 808 NW2d 67 (2012).

cancers, within human users and nonhuman test subjects. As the parties who tested, developed, designed, manufactured, marketed, sold, distributed and promoted Zantac® products which were defective and unreasonably dangerous and which had been so proven in tests known to Defendants but not known to the general public, Defendants had, but breached their duty to provide adequate warnings or instructions concerning the dangerous characteristics and risks of Zantac®.[46] They did not do so.

60. Each Defendant is charged with responsibility for having research developed, designed, tested manufactured, inspected, labeled distributed, marketed, promoted, sold, and otherwise released Zantac® into the stream of commerce. While doing so, they presented Zantac® as an approved substance that was beneficial, not harmful, to users. They disclosed no risk of:

60.1. Development of NDMA.

60.2. The risks of NDMA.

60.3. Development of cancer in human users.

60.4. The propensity to develop a substance within the human body that is carcinogenic and causes cancer.

60.5. The adverse consequences on health for the use of NDMA producing Zantac® including cancers requiring intensive medical intervention, and posing risks of debilitation, loss of critical organs, permeant impairments, and death.

61. The duty to warn by each Defendant was ongoing. Defendant BIP had this duty before the Sanofi Defendants, but the Sanofi Defendants as successors with joint and several successor liability and are parties with a duties and responsibilities to engage in, perform and complete independent investigations and make independent warnings, and disclosures to the public, as well to regulatory officials. At the time manufacture by each Defendant, that Defendant could have provided the warnings or instructions regarding the

[46] *Stahlecker v. Ford Motor Co.,* 266 Neb 601, 667 NW2d 244 (2003) Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 7 (2010), and Restatement (Second) of Torts § 402A. Also, *Jay v. Moog Automotive, Inc*., 264 Neb 875, 652 NW2d 872 (2002)(defective design).

risks of Zantac® but did not do so. Despite being warned by extensive publicly accessible scientific literature, the Defendants knew or should have known as pharmaceutical companies that Zantac® creates NDMA and NDMA produces cancer in the human body. Defendants withheld this information, or they failed to investigate, study, test or promote the safety or minimize the dangers, to Zantac® consumers who would foreseeably be harmed by Zantac®. These consumers included Plaintiff.

62. The Defendants joint and several failures to discharge their duties to disclose adequate warnings to consumers proximately caused Plaintiff's cancer which resulted from carcinogenic NDMA in his body. Plaintiff has no other predisposing factors and Zantac® was a substantial contributing cause to the development of cancer to Plaintiff's body.

63. Neither, Plaintiff could have discovered the defects or risks associated with Zantac®. Instead, Plaintiffs relied upon the skills, superior, knowledge and judgment of the Defendants to know about and disclose serious health risks associated with their products.

64. Zantac®'s label does not make adequate, suitable, or required disclosures. It did not so throughout the course of its marketing from and after 2006 through March 20, 2020 when Zantac® was withdrawn from the market.

65. The failure to warn committed by the Defendants on Zantac® labeling included:

65.1. Noncompliance with federal law;

65.2. Noncompliance with state law;

65.3. Failure to disclose known risk associated with Zantac®;

65.4. False statements about Zantac®'s safety;

65.5. Concealment of Zantac®'s dangers and risks of harm.

66. As a direct, proximate result both Plaintiff have suffered great mental anguish and Plaintiff sustained personal injuries, including illness, disease, need for extensive medical treatment intervention and care, special damages including loss income, loss earning capacity, medical costs and costs incidental thereto, and other special damages. She also suffers from depression, stress and mental anguish over her inestimable loss of

life and livelihood, concern about his ability to support herself and her family going forward, and near certain loss of life expectancy. Plaintiff and her spouse have a fifteen (15) years old grandson who has lived with him substantially of his life and is dependent upon them.

Second Theory: Strict Liability in Tort

67. All allegations above are renewed here.

68. Defendants are strictly liable in tort to Plaintiffs for defective design of their Zantac® products.

69. At relevant times, the Defendants engaged in the research testing, development, designing, manufacturing, marketing, selling, distributing, promoting, registering, labeling, and reporting matters related to Zantac® products and the products themselves. These Zantac® products included the ones used by Plaintiff. As alleged above the products were inherently and unreasonably dangerous. They contained substances that were foreseeable known to produce extremely high levels of NDMA in the human body. NDMA is a known dangerous carcinogen. It produced, and Defendants knew it produced, renal, biliary, hepatic, intestinal, blood born, and other cancers in the bodies of human users as reported and in scientific and medical literature, and in laboratory animals as reported in scientific testing literature, all of which were ignored and denied by Defendants.

70. Rather than make appropriate reports and disclosures to the public, Defendants suppressed and concealed this information and diminished its availability. For example, Defendants knew or should have known that a 2016 study at Stanford University gave 10 healthy volunteers 150 milligrams of Zantac® and found that subsequent NDMA levels in their urine exceeded 47,000 nanograms.[47]

71. Zantac® products were unreasonably dangerous when they were placed by each Defendant into the stream of commerce. Each Defendant during the times relevant as described above ultimately controlled and supervised these actions and each Defendant did design, research, development and manufacture produce assemble, label, advertise,

[47] See Fn 15.

promote and market and sell and distribute Zantac® products used by Plaintiff. Defendant BIP described Zantac® as safe and Sanofi perpetuated this description without making any corrections. Yet, Zantac® was known to be associated with elevated levels of cancer.

72. The Zantac® products to which Plaintiff was exposed in which he injected and were designed made and produced by Defendants, were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate. The risks and dangers of Zantac® exceeded the benefits allegedly associated with it. Exposure to Zantac® presents a risk of harmful side effects that outweighs any potential utility stemming from its use. Zantac® reached Plaintiffs with the defects in it when placed in the stream of commerce. Plaintiff used it as recommended and intended without changes.

73. Defendants knew or had to reason to know that its Zantac®'s products were defective and inherently and dangerous and unsafe when used in the manner instructed and provided by them and represented on their label, all of which existed when they placed Zantac® in the stream of commerce. The products were:

73.1. Defective in design in formulation and consequently dangerous to an extent beyond which an ordinary consumer would contemplate.

73.2. Unreasonably dangerous in that they were hazardous and posed grave risks of cancer of multiple types to foreseeable users, using the products as anticipated.

73.3. They failed to test, investigate or study the hazards of Zantac® and its propensity to produce NDMA in the human body and to appreciate that NDMA would cause cancers in foreseeable users including Plaintiff.

73.4. They failed to conduct post market surveillance of Zantac® in reasonable manner and to identify risks and adjust or withdraw it from the market but instead continued to sell it.

74. At all relevant times Plaintiff used Zantac® as intended and in the appropriate foreseeable manner as consumer. Zantac® reached Plaintiff in the same

condition in which left the control of each Defendant and was reasonably and responsibility used by Plaintiff.

75. Zantac® is more dangerous than alternative products that do not produce dangerous levels of NDMA in the body. Defendants knew this and knew that less risky alternatives to use as antacids were available. They also knew that using the alternatives would have prevented the harm and cancer from which Plaintiff suffers.

76. Zantac® was at all relevant times defective in design and/or formulation due to its inherent risk of producing the carcinogen NDMA and thereby rendering the drug unreasonably dangerous. Zantac® is defective because the substances of which it is compounded include inherently unstable ranitidine in molecular form containing both nitrate and dimethylamine in groups that combine to form NDMA as alleged.[48]

77. Each Defendant had a duty to use due care in designing and manufacturing Zantac® and to disclose known defects. Further, each Defendant had a duty to withhold from the market inherently dangerous products, whether the dangers were disclosed or not.[49]

78. The designed effect in Zantac® existed in the drug each time each shipment left each Defendant who shipped it during the period of that Defendant's ownership and control and at the time during which Plaintiff was purchasing and using Zantac®. Zantac® was expected to, and did reach, Plaintiff without a substantial change from the condition in which Zantac® was sold. It was used for its foreseeable intended purpose, in the way Defendants each recommended that it be used and for the purposes recommended.

79. Plaintiffs each sustained the damages for which they sue was a direct proximate result of the condition in which Zantac® was marketed and sold. Each Defendant is strictly liable in tort to Plaintiff because of the defective condition in which Zantac® was placed in the stream of commerce.

---

[48] Nebraska recognizes that FDA approval does not entitle a pharmaceutical company to blanket immunity from strict liability in tort. *Freeman v. Hoffman La-Roche, Inc.,* 260 Neb 552, 555-569, 618 NW2d 827, 835-841 (2000).

[49] Nebraska recognizes a common law duty to use due care so as to not negligently injure another person. *Wilke v. Woodhouse Ford, Inc.,* 278 Neb 00, 810, 774 NW2d 370, 379 (2009).

80. Defendants acted willfully and wantonly, fraudulently, maliciously. They conducted themselves with abruptness disregard for the health and safety users of Zantac® including Plaintiffs. Defendants risked the lives of consumers and users of Zantac® for profits and concealed its dangers with a profit motive to do so.

81. Plaintiffs' damages are accruing. Leave is requested to amend the Complaint to state the total amount of special damages at the time of the final pretrial conference or at trial.

Third Theory: Negligence

82. All allegations above are renewed here.

83. Each Defendant owed a duty of reasonable care to all foreseeable users of their Zantac® products, including Plaintiff, but each breached the duty of reasonable care. The breaches proximately caused Plaintiffs' damages.[50]

84. Zantac® was available for over the counter purchase in 75 mg and 150 mg pills and by prescription for 300 mg pills or other dosages. It was sold over the counter in multiple forms. However, the predominate portion of Zantac® products used by Plaintiff were prescribed and dispensed as prescriptions. The prescriptions were not by injection to the best of Plaintiffs recollection. It was sold in at least these forms:

Zantac®

Zantac® 150

Zantac® 150 Acid Reducer

Zantac® 150 Maximum Strength

Zantac® Maximum Strength Cool Mint

Zantac® 75

Zantac® 75 Regular Strength

Zantac® Maximum Strength 150 Cool Mint

Zantac® (Ranitidine Injection)

Zantac® (Ranitidine Syrup)

[50] *Deviney v. UPRR,* 280 Neb 450, 786 NW2d 902 (2010).

Zantac® (Ranitidine Tablets & Capsules)

Zantac® Cool Mint

Zantac® Injection

85. Each Defendant caused Zantac® products to be sold, distributed, packaged, labeled, marketed and promoted to Plaintiffs and other foreseeable users. By undertaking these activities, each Defendant owed to Plaintiffs and the public the duties:

85.1. To exercise reasonable care in the design, research manufacture marketing advertising supply for motion packaging sale and distribution, labeling, and description of its submissions to regulators of their Zantac® products. This included the duty to undertake all steps reasonable and necessary to assure that these Zantac® products were not unreasonably dangerous to consumers.

85.2. To exercise reasonable care in the marketing advertisement labeling and sale of Zantac® products including a duty to warn the consumers and general public of the risks and hazards associated with Zantac®, its action within the human body, its production of NDMA, the carcinogenic properties of NDMA and the contraindications, adverse effects, and life-threatening damages that were likely to result from its use because of Zantac® carcinogenic properties.

85.3. To warn of know risks and risks disclosed by scientific research.

85.4. To withhold the product from the market.

85.5. To exercise reasonable care and marketing and representation of the product.

85.6. To refrain from falsifying, withholding, or manipulating unfavorable research data or fining favorable research data or results.

85.7. To label its product with complete disclosures of the risks.

85.8. To make disclosures to physicians about the risks and dangers of its product so they could fulfill their function as learned intermediaries. Instead it misled them.

86. Each Defendant breached each of these duties and was negligent by failing to fulfill each of them. Instead, each Defendant negligently:

86.1. Designed, formulated, labeled, marketed, promoted and sold its Zantac® products.

86.2. Submitted, or withheld and failed to submit, relevant research information concerning the hazards and risks of Zantac® to government regulatory authorities.

86.3. Failed to recall its Zantac® products.

86.4. Manufactured Zantac®.

86.5. Designed and tested Zantac®.

86.6. Packaged Zantac®.

86.7. Marketed, advertised, and commercialized Zantac®.

86.8. Failed to provide adequate instructions, guidelines or safety precautions to foreseeable users

86.9. Failed to inform of safer alternatives known to exist.

86.10. To make disclosures to physicians about the risks and dangers of its product so they could fulfill their function as learned intermediaries. Instead it misled them.

87. These negligent acts and omissions occurred and were committed by each Defendant. Defendants did so when they each knew of the risks associated with Zantac® including the development NDMA, carcinogenetic consequences on the human body, and the development of lethal cancers including renal cancer. Defendants also misrepresented Zantac® and known carcinogenetic properties and associations from the medical community, including Plaintiffs providers.

88. Each Defendants conduct was negligent, but each also acted recklessly. Each made conscious decisions to withhold action and to decline to withdraw, recall, relabel, warn, inform regulators, or otherwise take appropriate steps to protect the public and foreseeable users including Plaintiff.

89. As a proximate result of these acts and omissions, Plaintiffs sustained the damages for which they sue.

Fourth Theory: Breach of Express Warranty

90. All allegations above are renewed here.

91. Defendants' public statements descriptions and promises relating to Zantac® constituted express warranties that Zantac® was safe and effective for its intended use and was designed and sold to prevent or relieve heartburn associated with acid indigestion and a sour stomach, or as a reaction to certain ingested foods or beverages.

92. Each Defendants' expressed warranties were made in the form of:

92.1. Public written and verbal assurances that Zantac® was safe.

92.2. Press releases and media statements describing Zantac® and its safety.

92.3. Verbal assurances made by Defendants' marketing personnel about the safety of Zantac® including statements made to pharmacists, physicians, and other health care providers for the purpose of having those statements repeated without investigations.

92.4. On the Zantac® box, and label and packaging materials.

92.5. Made the foregoing assurance to physicians as well as the public at large, for the purpose of having them repeated and relied upon by physicians including those prescribing for Plaintiff.

93. In each and all these materials, Zantac® was promoted as the best treatment available as an antacid and as a safe H2 blocker. Specific statements by Defendants about Zantac® included the statement that:

93.1. It relieved heartburn associated with acid indigestion and sour stomach and heartburn associated with eating certain foods:

93.2. Should not be used if one had suffered an allergic reaction to ranitidine or other acid reducers or had kidney disease except under a physician's advice, or if a person considering its use was pregnant or

breast feeding, in which case it should be used only after asking a health professional.

93.3. Active ingredients included Hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin.

These descriptions of the product were made by all Defendants.[51]

94. The prescription Zantac® contained disclosures to physicians but did not disclose carcinogenic properties. Consistent with the package insert, Zantac® clinical pharmacology was described without any description of the development of NDMA or risks of carcinogen in the human body. Indeed, the package insert affirmatively represented that:

94.1. Zantac® "does not affect pepsin secretion and has no significant effect on pentagastrin-stimulated intrinsic factor secretion and little or no effect on fasting or postprandial serum gastrin".

94.2. Zantac® should be adjusted in patients with impaired renal function and caution should be observed in patients with hepatic dysfunction but there was no indication that it should not be used in such patients.

94.3. The package insert further affirmatively represented "there was no indication of tumorigenic or carcinogenic affects in life-span studies in mice and rats at oral dosages up to 2,000 mg/kg/day".

95. While adverse reactions were described, none of the adverse reactions included the development of cancers even though laboratory and human studies had provided abundant contrary data. These statements were made about Zantac® by Defendant GlaxoSmithKline as late as April 2009, and thereafter within the period of the

[51] It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty. § 2–313(2). *Hillcrest Country Club v. N.D. Judds Co.,* 236 Neb. 233, 461 N.W.2d 55 (1990).

statute of repose. The foregoing statements were affirmations of fact and descriptions of the product.[52] Plaintiffs reasonably relied on Defendants' affirmations of fact and descriptions though they were not accurate. Instead, Zantac® produces lethal carcinogenic and dangerous levels of NDMA in the human body which in turn produces life threatening, and fatal cancers.

96. Each Defendant breached the foregoing express warranties because in each instance the warranties were incomplete, not placed in proper context in the light of the things that were said about the product and were false.[53]

97. Plaintiffs justifiably relied on the express warranties and representations of each Defendant as they purchased the product and Plaintiff used it over the years. When decision purchases were made, reliance was placed upon the expressed warranties of the Defendants. The Defendants were merchants with respect to products like and including Zantac®, and Plaintiffs were members of the consuming public who had to and did rely upon them for their knowledge, experience and expertise in formulated pharmacological drugs like and including Zantac®. [54]

98. The harm caused by Zantac® far outweigh its benefits rendering it more dangerous than an ordinary consumer or user, including Plaintiffs, would expect, and more dangerous than available alternative products.

99. As a direct proximate result of the acts and omissions of the Defendants, Plaintiffs sustained the damages for which they sue.

Fifth Theory: Breach of Implied Warranties

100. All allegations above are renewed here.

101. Each Defendant placed Zantac® on the market and in the stream of commerce with the implied warranty that Zantac® was merchantable and was also fit for

---

[52] Neb UCC § 2-313(a) and (b).

[53] Whether or not an express warranty arises under the UCC and whether express or implied warranties are breached are questions of fact to be determined by the trier of fact. See *Hillcrest Country Club v. N.D. Judds Co.,* 236 Neb. 233, 461 N.W.2d 55 (1990) (creation of express warranty); *Ruskamp v. Hog Builders, Inc.,* 192 Neb. 168, 219 N.W.2d 750 (1974) (whether there has been breach of warranty, express or implied, is largely question of fact).

[54] *Id.*; Neb UCC § 2-318.

its intended purpose as a medication that would prevent or reduce antacid, and the adverse consequences of stomach acids and sour stomach. Furthermore, Plaintiffs relied upon the implied warranties that Zantac® was fit to pass in the over-the-counter pharmaceutical trade without objection as to its quality and perform as represented.

102. Defendants' implied warranties were breached. The product, Zantac® , was not of merchantable quality and not safe and fit for the use for which it was intended. It was not fit for use as an antacid because it is carcinogenic and causes to be introduced lethal cancer-producing levels of NDMA in the system.

103. The harm caused by Zantac® far outweigh its benefits rendering it more dangerous than an ordinary consumer or user, including Plaintiffs, would expect, and more dangerous than available alternative products.[55]

104. As a direct, proximate result of these breaches of warranty, Plaintiffs sustained the damages for which they sue.

Sixth Theory: Nebraska
***Deceptive Trade Practices Act*, *Neb Rev Stat* §§ 87 – 301 et. seq.**

105. Allegations above are renewed here.

106. Zantac® is an article within the meaning of *Neb Rev Stat §* 87-301(3) and it contains products that act as carcinogens in the human body. Zantac® was represented as safe. It did so with television "Fireman" commercials, and with other advertisements.[56]

107. Each Defendant engaged in deceptive trade practices when in the course of its business it:

107.1. Represented that Zantac® had approval characteristics, ingredients, uses, benefits or qualities that it did not have.

---

[55] Proof of negligence establishes breach of implied warranty. *Adams v. American Cyanamid Co*., 1 Neb. App. 337, 498 N.W.2d 577 (1992). *El Fredo Pizza, Inc. v. Roto-Flex Oven Co,* 199 Neb 697, 261 NW2d 358 (1978); *Christensen v. Eastern Nebraska Equip Co.,* 199 Neb 741, 261 NW2d 367 (1978).

[56] "Fireman" video of September 2015 available at https://www.google.com/search?biw=1280&bih=557&tbm=vid&ei=OIKkXuXcKMXWtQbswbCAAQ&q=zantac+commercial+tv+2015&oq=zantac+commercial+tv+2015&gs_l=psy-ab.12...14961.23044.0.25020.5.5.0.0.0.0.180.732.0j5.5.0....0...1c.1.64.psy-ab..0.1.180...33i299k1j33i160k1.0.GNXJPv1_srI - last visited 4.25.2020, and at https://www.ispot.tv/ad/AkgC/zantac-firefighter - last visited 4.25.2020.

107.2. By implication that it was not carcinogenic though it was.

107.3. Zantac® was of superior quality and safe for use as an antacid or an acid reducer and for other purposes expressed on its label and package inserts when it was not because it was carcinogenic.

107.4. Made false statements concerning its safety and concealed it carcinogenic properties.

108. Defendant's acts and omissions constitute deceptive trade practices within the meaning of the Nebraska *Deceptive Trade Practices Act.*

109. Each Plaintiff is a person damaged by the deceptive trade practices of the Defendants and entitled to relief in the form of monetary damages as his purchased and used Zantac® and was diagnosed with cancer caused by it within four (4) years of this action. During those four (4) years, Zantac® was sold by the Sanofi Defendants and Defendant BIP, and they engaged in the deceptive practices at issue during this time.[57]

First Claim: Mrs. Jackson

110. All allegations above are renewed here. Plaintiff invokes all theories described above.

111. As a direct proximate result of each and all wrongful acts of each Defendant, Plaintiff sustained the general and special damages described above. She contracted cancer and is both temporarily and permanently impaired and suffers physical and emotional pain and anguish which will be ongoing and life long, as well as a shortened life expectancy.

112. Plaintiff seeks general and special damages from each and all Defendants jointly and severally. Her general damages include temporary and permanent loss of stamina, strength, ability to perform his work and activities of daily living, debilitation of her health and quality, lost earnings and lost earning capacity, limiting and disabling healthcare interventions for her cancer, enhanced of vulnerability to viruses and diseases including the novel Corona virus known as COVID-19, emotional distress, anxiety, depression, fear of uncertainty, and probable loss of life expectancy. Her special damages

[57] *Neb Rev Stat* § 87-303.10.

include lost earnings and lost future earnings, medical care costs and expenses, costs for medications and treatments, travel and related expenses for medical care, and the need for legal expenses. Her special damages are accruing. Leave to amend this Complaint to state the special damages as of the time of the final pretrial conference, or at trial, is requested. Plaintiff special damages are expected to be substantial she experienced a complex surgical procedure in June 2020. The procedure includes removal of her bladder and other organs.

Second Claim: Mr. Jackson

113. All allegations above are renewed here.

114. As a direct proximate result of the foregoing acts and omissions, Daniel Jackson, spouse of Karen Ellen Jackson, sustained general damages because of the loss of his wife's care, comfort, companion, society, support, services, advice, counsel, love and affection. These are consortium[58] damages which she suffers as a derivative result of his wife's injuries. Mr. Jackson seeks general damages.

Requests for Relief

On the foregoing basis, Plaintiffs seek:

115. For Mrs. Jackson, general and special damages on Plaintiff's first claim.

116. For Mr. Jackson judgment on their second claim for general damages.

117. For both Plaintiffs on each claim, taxable costs, prejudgment interest as allowed by law and attorneys' fees.

118. Plaintiffs request leave to amend this Complaint to detail their special damages at the time of the final pretrial conference. They also request leave to amend this Complaint in the event a motion to dismiss is sustained due to a defect in the pleading.

Jury Demand

119. Plaintiffs respectfully demand trial by jury. If this case is not tried in the state court system in Nebraska Plaintiffs demand trial in Omaha, Nebraska nearby where

[58] "We have defined consortium to mean comfort, society, love, and protection. *[Citations omitted.]* We have long held that a husband may recover for the loss of his nonfatally injured wife's consortium, *Omaha & R. V. R. Co. v. Chollette,* 41 Neb. 578, 59 N.W. 921 (1894), and permit a wife to recover for the loss of her nonfatally injured husband's consortium, *Anson v. Fletcher,* 192 Neb. 317, 220 N.W.2d 371 (1974)." G*uenther by Guenther v. Stollberg*, 242 Neb. 415, 416, 495 N.W.2d 286, 286 (993).

Plaintiffs reside, and the location most convenience for medical providers most and witnesses. In the federal system this case would be related to MDL 2924.

Karen Ellen Jackson &Daniel Jackson,
Plaintiffs

By: /s/ *David A. Domina,* #11043
Domina Law Group pc llo
2425 S. 144th St. Omaha, NE 68144
(402) 493-4100

Plaintiffs' Lawyers